IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

GAYATHRI MURTHY, Plaintiff, v. ABBOTT LABORATORIES, Defendant.	)	Case No. 4:11-cv-00105-KPE Hon. Keith P. Ellison

DEFENDANT ABBOTT LABORATORIES' NOTICE OF SUPPLEMENTAL AUTHORITY IN OPPOSITION TO PLAINTIFF'S MOTION FOR RELIEF FROM JUDGMENT

Defendant Abbott Laboratories ("Abbott") makes this supplemental submission in support of its opposition to plaintiff's motion for relief from judgment to inform the Court regarding the recent testimony on September 11, 2012 by plaintiff's own rheumatology expert, M. Eric Gershwin, Chief, Division of Rheumatology and Professor of Medicine at University of California at Davis.

The sole basis for plaintiff's claim that she can satisfy in this case the "off label" promotion exception to Section 82.007 of the Texas Civil Practice and Remedies Code is found in paragraphs 16 and 17 of the proposed Second Amended Complaint. In those paragraphs plaintiff pleads in a conclusory fashion that Abbott promoted Humira for an off label use because its sales representatives allegedly urged plaintiff's doctor to prescribe Humira for "early" RA, which plaintiff claims is equivalent to mild RA, a non-approved indication. Dr. Gershwin's testimony further refutes this basic premise of plaintiff's motion—i.e., that use of Humira for "early RA" constitutes an "off-label" use because Humira was approved only for moderate to severe RA.

Dr. Gershwin testified that there is a distinction between disease *duration* (i.e., whether the disease is "early RA") and disease *severity* (i.e., whether the disease is "moderate" or "mild"). Accordingly, he agrees that there is "no question" that "treatment of early RA" with anti-TNFs in patients who have moderate, severe or aggressive disease is consistent with both the "current thinking regarding the standard of care" and "the label":

> Q. Treatment of early RA with anti-TNFs is consistent with the current thinking regarding the standard of care and the label; correct?
>
> A. Yeah, if they—if they meet appropriate criteria for a study. You're talking about the treatment of patients. Yeah, I agree if patients have moderate and severe rheumatoid arthritis, they have aggressive disease, they should be treated with anti-TNFs. No question about it.
>
> Q. And the earlier the better?
>
> A. If you want—if you have a patient who has got aggressive disease, absolutely. The earlier the better.

(Dr. Gershwin 9/11/12 Dep. at 437:01-13 (Exhibit 1).) As Dr. Gershwin explained, treatment of early RA is necessary "to avoid structural damage":

> Q. The—do you agree that you want to treat patients with RA early to avoid structural damage?
>
> A. Absolutely.
>
> Q. And you want to treat patients with RA early with anti-TNFs to avoid structural damage?
>
> A. If they don't respond to Methotrexate, absolutely.

(*Id.* at 340:21-341:02.) As he noted, rheumatoid arthritis patients who achieve remission within the first year "can become virtually symptom free," avoiding the structural damage that results in "permanent disability":

> Q. Patients who undergo remission in the first year can become—of RA can become virtually symptom free. But once structural damage occurs, there will be permanent disability; correct?

A. I would agree with that.

(*Id.* at 341:07-11.) In sum, Dr. Gershwin's testimony confirms Abbott's showing in opposition to plaintiff's motion that there is no basis for plaintiff's contention that promotion of treatment of "early RA" is equivalent to promoting use of Humira for mild RA and is therefore an off-label use of Humira. As Dr. Gershwin's testimony makes clear, use of Humira to treat individuals with early RA who have moderate, severe, or aggressive disease is consistent with the label and dictated by the standard of care. Plaintiffs' conclusory allegations of off label promotion cannot pass muster under *Iqbal* and *Twombly*. *See, e.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (holding that "conclusory statements" "do not suffice" under Federal Rules); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007) ("conclusory allegation" insufficient to meet pleading standards under Federal Rules).

Dated: September 14, 2012

Respectfully submitted,

/s/ Michael P. Foradas

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing DEFENDANT ABBOTT LABORATORIES' NOTICE OF SUPPLEMENTAL AUTHORITY IN OPPOSITION TO PLAINTIFF'S MOTION FOR RELIEF FROM JUDGMENT was filed electronically on this 14th day of September 2012, and will, therefore, be served electronically upon:

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